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FRANK P. BECKING
BOZICEVIC, FIELD & FRANCIS, LLP
200 MIDDLEFIELD ROAD
SUITE 200
MENLO PARK, CA 94025

EXAMINER	
MILLER, CHERYL L	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 21

Application Number: 09/828,539
Filing Date: April 04, 2001
Appellant(s): PREISSMAN, HOWARD

Frank P. Becking (Registration No. 42,309)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 10, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 33-34 and 36 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The rejection of claims 37-39 and 46 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The rejection of claim 35 stand or fall alone because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The rejection of claims 40-44 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The rejection of claims 47-51 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The rejection of claims 52-53 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,258,028	ERSEK et al.	11-1993
6,080,801	DRAENERT et al.	6-2000
5,336,699	COOKE et al.	8-1994

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 40-44 are rejected under 35 U.S.C. 102 (b) as being anticipated by Ersek et al. (USPN 5,258,028). Ersek discloses a flowable matrix (31) and radiopaque particles (30), (col.3,

lines 7-8, 15-18; col.10, lines 23-26) having a size between 350μ and 2200μ, 570μ and 2200μ, 450μ and 1600μ, or 570μ and 1150μ (col.5, lines 43-45), and further having smaller particles having a size between 120μ and 350μ (col.5, line 64-col.6, line 2).

Claims 33-39 and 46 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Draenert et al. (USPN 6,080,801) in view of Ersek et al. (USPN 5,258,028). Referring to claim 33, Draenert discloses a composition comprising a biocompatible matrix (col.3, lines 22-29), radiopaque particles, and a liquid contrast agent (liquid and/or solid contrast agents, col.3, lines 58-64). Draenert does not disclose however, particles having a size of 120μ to 2200μ. Ersek teaches radiopaque particles having an increased size of 120μ to 2200μ, in order to optimize the size for aiding in injection, and avoiding the adverse effects of smaller particles (col.3, line 60-col.4, line 44; col.6, lines 8-12). Because Ersek's particle sizes are injectable, Draenert's composition of even smaller particles is inherently injectable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Draenert's composition including radiopaque particles, with Ersek's teaching of increased particle size, in order optimize size to aid in injection.

Referring to claim 34, Draenert discloses matrix and particles forming a slurry (admixture, col.2, line 50; col.4, lines 38-44).

Referring to claim 35, Draenert discloses a mixture of matrix and particles forming a hard tissue implant (col.1, lines 18-24).

Referring to claims 36-39, Ersek teaches particles having a size of between 350μ and 2200μ, 570μ and 2200μ, 450μ and 1600μ, or 570μ and 1150μ (col.5, lines 43-45) for the reasons above, and further having smaller particles having a size between 120μ and 350μ in order to

provide variation in size to ease injection and to take into account normal variation from patient to patient so that the composition may be used with all patients in various locations (col.5, line 64-col.6, line 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Draenert's composition having radiopaque particles, with Ersek's teaching of optimal particle size with particle variation, in order to provide smaller and larger particles in order to ease the injection and take into account patient and implant location variation, so that the composition may be used with all patients and at various tissue sites of all sizes.

Claims 47-53 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Cooke et al. (USPN 5,336,699) in view of Ersek et al. (USPN 5,258,028). Referring to claims 47 and 49-53, Cooke discloses an injectable composition (col.8, lines 28-31) comprising a hard tissue implant biocompatible matrix (col.2, lines 58-61) and radiopaque particles mixed within the matrix (col.1, lines 18-19). Cooke does not disclose however, particles having a size between 120μ and 2200μ, 350μ and 2200μ, 450μ and 1600μ, 570μ and 1150μ, and additional particles having a size between 120μ and 350μ or up to 350μ. Ersek teaches radiopaque particles having a size between 120μ and 2200μ, 350μ and 2200μ, 450μ and 1600μ, 570μ and 1150μ, and additional particles having a size between 120μ and 350μ or up to 350μ in order to increase the size (optimizing), which in turn aids in injection (col.3, line 60-col.4, line 44; col.6, lines 8-12) and provides variation in size (smaller and larger particles) taking into account normal variation from patient to patient and implant location (col.5, line 64-col.6, line 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the composition of Cooke including radiopaque tissue particles, with Ersek's particle size and size

variation for tissue implants, in order optimize size, in turn aiding in injection, and to optimize the use from patient to patient, and tissue location to tissue location.

Referring to claim 48, Cooke discloses a matrix and particles forming a slurry (intermixed, col.8, lines 65-69; col.4, lines 55-60).

(11) Response to Argument

Applicant has argued that Ersek does not anticipate claims 40-44 because Ersek fails to disclose a composition containing particles in two size ranges. The examiner responds by noting that the applicant has not claimed two distinct size ranges. Claim 40 recites "radiopaque particles having a size between *about* 350μ and about 2200μ" and "radiopaque particles for contrast having a particle size up to *about* 350μ". The first "range" begins around *about 350μ.* The second "range" ends around *about 350μ.* Therefore, the first and second ranges overlap around about 350μ. Being an overlap, one "range" exists, not two distinct ranges. Ersek discloses radiopaque particles having a size of between 30μ and 3000μ (col.4, lines 2-3). Ersek also discloses the particles varied over a range so that there will be some larger particles and some smaller particles than the target size in any combination (col.5 line 64- col.6 line 2). Although the Examiner agrees that Ersek teaches the concept of random variation about an optimal particle size, if Ersek were to chose 350μ as the optimal target size (which falls within Ersek's range of between 30μ and 3000μ), some particles would be smaller than 350μ and some particles would be above 350μ, which would fall within the recited "two ranges" that applicant has claimed. Therefore, the examiner believes that Ersek still anticipates claims 40-44.

Applicant has argued that Ersek's teachings do not apply as a motivation for combination with Draenert (claims 33-39 and 46) or Cooke (claims 47-53), because one would not be motivated to use Ersek as a teaching for an increase in particle size because Ersek's composition is not for use as a hard *tissue* implant, Ersek being non-analogous art. The examiner disagrees. First, Ersek, Draenert and Cooke all teach an implant for injection into a *body tissue*. Second, Ersek discloses soft and hard tissues as being analogous arts (col.1, lines 39-46, 60-63). Third, Ersek teaches the use of material for both soft and hard tissue applications (col.3, lines 52-60). Forth, Ersek makes use of similar materials (hydroxyapatite, ceramics, etc., col.3, lines 52-60) as Draenert (hydroxylapatite, ceramics, col.4, lines 9-12) and Cooke (PMMA, acrylates, col.2, lines 58-61), therefore the combination would be obvious to combine the references because they are all hard tissue materials (all materials listed above by Ersek, Draenert, and Cooke are disclosed in applicants appeal brief summary of the invention as being hard tissue materials, see pages 3-4). Therefore, the arts are analogous. Also, although Draenert focuses on particles sizes of 5μ-15μ (col.3, lines 29-30), Draenert also discloses the use of particles up to 250μ (col.3, lines 39-40), which falls within the range claimed by the applicant and would be obvious to combine with Ersek's teaching of increased size, because Draenert has hinted at the idea. Therefore, the examiner believes that the rejections of Draenert in view of Ersek and Cooke in view of Ersek are still combinable, they are indeed analogous art and the rejection is still applicable.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Cheryl Miller
November 14, 2003

Conferees
Corrine McDermott
John Calvert

FRANK P. BECKING
BOZICEVIC, FIELD & FRANCIS, LLP
200 MIDDLEFIELD ROAD
SUITE 200
MENLO PARK, CA 94025

JOHN J. CALVERT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700